JC03 Rec'd PCT/PTO 1 2 OCT 2005

FORM PTO-1390 (Modified) U.S. PATENT AND TRADEMARK OFFICE; U.S. DEPARTMENT OF COMMERCE (REV. 2-2005)

## TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

ATTORNEY'S DOCKET NUMBER PB60212USW

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

| C        | ON   | ICERNING A SUBMISS  | ON UNDER 35 U.S.C. 371   | 10/552869                              |  |  |  |  |  |  |  |  |
|----------|--|---|--|--|--|--|--|--|--|--|--|--|
| NTEF     |  | IONAL APPLICATION NO. PCT/EP04/004126   | INTERNATIONAL FILING DATE April 16, 2004   | PRIORITY DATE CLAIMED April 17, 2003   |  |  |  |  |  |  |  |  |
| Comb     | OF II  | NVENTION ons Comprising Paroxetine and 2  | 2-(S)-(4-Fluoro-2-Methyl-Phenyl)-Piperazi  | ne-1-Carboxylic Acid                   |  |  |  |  |  |  |  |  |
|          |  | T(S) FOR DO/EO/US   | I DOME D   |  |  |  |  |  |  |  |  |  |
| MEL      | OFT  | O, Sergio; CORSI, Mauro; CAR  | and 2-(S)-(4-Fluoro-2-Methyl-Phenyl)-Piperazine-1-Carboxylic Acid henyl)-Ethyl!-Methyl Amide For Treatment of Depression and/or Anxiety  CARLETTI, Renzo  States Designated/Elected Office (DO/EO/US) the following items and other information: of items concerning a submission under 35 U.S.C. 371.  SEQUENT submission of items concerning a submission under 35 U.S.C. 371.  to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (7), (7), (7), (7), (7), (7), (7), (7 |  |  |  |  |  |  |  |  |  |
| Applic   | ant h  | erewith submits to the United State   | s Designated/Elected Office (DO/EO/US) the   | following items and other information: |  |  |  |  |  |  |  |  |
| •        | _  |   |  |  |  |  |  |  |  |  |  |  |
| 1.       | ⊠<br>□   |   |  |  |  |  |  |  |  |  |  |  |
| 2.<br>3. |  | •   |  |  |  |  |  |  |  |  |  |  |
| ٥.       | _  | (9) and (24) indicated below.   |  |  |  |  |  |  |  |  |  |  |
| 4.       | $\boxtimes$  | The US has been elected (Article 31).   |  |  |  |  |  |  |  |  |  |  |
| 5.       | 5. A copy of the International Application as filed (35 U.S.C. 371 (c)(2)) |   |  |  |  |  |  |  |  |  |  |  |
|          |  | a.  is attached hereto (requ  | ired only if not communicated by the Internat  | ional Bureau).                         |  |  |  |  |  |  |  |  |
|          |  | b. 🛛 has been communicated by the International Bureau.   |  |  |  |  |  |  |  |  |  |  |
|          |  | c.  is not required, as the application was filed in the United States Receiving Office (RO/US).  |  |  |  |  |  |  |  |  |  |  |
| 6.       |  | An English language translation of  | f the International Application as filed (35 U.S   | i.C. 371(c)(2)).                       |  |  |  |  |  |  |  |  |
|          |  | a.  is attached hereto.   |  |  |  |  |  |  |  |  |  |  |
|          |  | b.  has been previously submitted under 35 U.S.C. 154(d)(4).  |  |  |  |  |  |  |  |  |  |  |
| 7.       | $\boxtimes$  |   | • •  |  |  |  |  |  |  |  |  |  |
|          |  | a.   are attached hereto (rec   | uired only if not communicated by the Interna  | itional Bureau).                       |  |  |  |  |  |  |  |  |
|          |  | b.  have been communicated by the International Bureau.   |  |  |  |  |  |  |  |  |  |  |
|          |  | c. have not been made; ho   | owever, the time limit for making such amendi  | ments has NOT expired.                 |  |  |  |  |  |  |  |  |
|          | _  |   |  |  |  |  |  |  |  |  |  |  |
| 8.       |  | An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).                                     |  |  |  |  |  |  |  |  |  |  |
| 9.       |  | An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).   |  |  |  |  |  |  |  |  |  |  |
| 10.      | Ц  | An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)). |  |  |  |  |  |  |  |  |  |  |
| 11.      |  | A copy of the International Preliminary Examination Report (PCT/IPEA/409).  |  |  |  |  |  |  |  |  |  |  |
| 12.      | $\boxtimes$  | A copy of the International Search  | Report (PCT/ISA/210).  |  |  |  |  |  |  |  |  |  |
| Ite      | ems 1  | 3 to 23 below concern documen   | t(s) or information included:  |  |  |  |  |  |  |  |  |  |
| 13.      | $\boxtimes$  |   |  |  |  |  |  |  |  |  |  |  |
| 14.      |  | An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.                               |  |  |  |  |  |  |  |  |  |  |
| 15.      | $\boxtimes$  | A FIRST preliminary amendment.  |  |  |  |  |  |  |  |  |  |  |
| 16.      |  | ,   |  |  |  |  |  |  |  |  |  |  |
| 17.      |  | A substitute specification.   |  |  |  |  |  |  |  |  |  |  |
| 18.      |  | A power of attorney and/or change of address letter.  |  |  |  |  |  |  |  |  |  |  |
| 19.      |  |   |  |  |  |  |  |  |  |  |  |  |
| 20.      |  |   | nternational Application under 35 U.S.C. 154(  |  |  |  |  |  |  |  |  |  |
| 21.      |  | A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4).                                   |  |  |  |  |  |  |  |  |  |  |
| 22.      | ⊠<br>⊠   |   | 332063858 US   |  |  |  |  |  |  |  |  |  |
| 23.      | ×  | Other items or information:   |  |  |  |  |  |  |  |  |  |  |
|          | a) PCT Cover Page  |   |  |  |  |  |  |  |  |  |  |  |

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE to respond to a collection of information unless it displays a valid OMB control number.

| US ARRICATED TO THE STATE OF THE PERSONS OF THE PER |   |                                   | INTERNATIONAL APPLICATION NO.                |   |                 | ATTORNEY'S DOCKET NUMBER  |              |               |                 |  |  |  |
|--|---|-----------------------------------|--|---|-----------------|---------------------------|--------------|---------------|-----------------|--|--|--|
|  | PCT/EP04/004126   |                                   |  |   | PB60212USW      |                           |              |               |                 |  |  |  |
| _  | fees are submitte   |                                   |  |   |                 | CALCULA                   |              | PTO USE       |                 |  |  |  |
|  |   |                                   |  | • • • •   |                 | \$300                     | \$           | \$300.00      |                 |  |  |  |
| 25.  Examina If International pre satisfy provisions   | eliminary examination of PCT Article 33                         | \$                                | \$200.00                                     |   |                 |                           |              |               |                 |  |  |  |
| All other situation  | 3   |                                   |  |   |                 |                           |              |               |                 |  |  |  |
| Search fee (37 Cl<br>the USPTO as an   | fee<br>FR 1.445(a)(2)) ha<br>International Sea                  |                                   |  |   |                 |                           |              |               |                 |  |  |  |
| International Sear<br>All other situation  | ch Report prepare   | \$                                | \$400.00                                     |   |                 |                           |              |               |                 |  |  |  |
| ΤΟΤΔΙ  | OF 24, 25 and   | \$                                | \$900.00                                     |   |                 |                           |              |               |                 |  |  |  |
| ☐ Additional fe<br>sequence lis<br>\$250 for eac   | e for specification<br>ting or computer p<br>h additional 50 sh |                                   |  |   |                 |                           |              |               |                 |  |  |  |
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| CLAIMS   | NUMBER F  | IUMBER EXTRA                      | UMBER EXTRA RATE                             |   |                 |                           |              |               |                 |  |  |  |
| Total claims   | 21  | - 20 =                            | 1  | ×   |                 | \$50.00                   | \$           | \$50.00       |                 |  |  |  |
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| MULTIPLE DEPE  | NDENT CLAIMS  | (if applicable)                   |  | +   |                 | \$360.00                  | \$           | \$0.00        |                 |  |  |  |
|  |   | TOTA                              | L OF ABOVE C                                 | ALC   | ULA             | TIONS =                   | \$           | \$950.00      |                 |  |  |  |
| ☐ Applicant cla  | ims small entity s  | \$                                | \$0.00                                       |   |                 |                           |              |               |                 |  |  |  |
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| Fee for recording accompanied by   | the enclosed ass<br>an appropriate co                           | ignment (37 C<br>ver sheet (37 c  | FR 1.21(h)). The as<br>CFR 3.28, 3.31). \$40 | signn<br>) per  | nent m<br>prope | nust be<br>rty +          | \$           | \$0.00        |                 |  |  |  |
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| a.  A check in the amount of \$ to cover the above fees is enclosed.   |   |                                   |  |   |                 |                           |              |               |                 |  |  |  |
| b.   Please charge my Deposit Account No. 07-1392 in the amount of \$950.00 to cover the above fees.   |   |                                   |  |   |                 |                           |              |               |                 |  |  |  |
| ·  | ate copy of this sh<br>ctor is hereby aut                       |                                   | rge any additional fe                        |   |                 |                           |              | t any overp   | ayment          |  |  |  |
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| informa  | tion should not l   | oe included o                     | WARNING: Information this form. Provide      | credi   | it card         | l informatio              | n and author | ization on F  | PTO-2038.       |  |  |  |
| NOTE: Where a must be filed an   | n appropriate tin<br>d granted to res                           | ne limit under<br>tore the Interi | r 37 CFR 1.495 has i<br>national Application | not b   | een n<br>endin  | net, a petiti<br>g status | on to revive | e (37 CFR 1   | .137(a) or (b)) |  |  |  |
| SEND ALL COR   | RESPONDENCE   |                                   |  |   |                 |                           |              |               |                 |  |  |  |
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|  |   | TION NUMBER                       |  |   |                 |                           |              |               |                 |  |  |  |

JC20 Rec'd PCT/PTO 12 OCT Docket No. **CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10)** Applicant(s): Melotto et al. **PB60212USW** Filing Date Examiner Customer No. Group Art Unit Application No. To Be Assigned Concurrently Herewith 23347 Combinations Comprising Paroxetine and 2-(S)-(4-Fluoro-2-Methyl-Phenyl)-Piperazine-1-Carboxylic Acid '1-(R)-(3,5-BIS-Trifluoro-2-Methyl-Phenyl)-Ethyl!-Methyl Amide For Treatment of Depression and/or Anxiety Invention: I hereby certify that the following correspondence: National Phase Application with accompanying papers (Identify type of correspondence) is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on ) Ctober 12, 2005 Valerie L. Phillips (Typed or Printed Name of Person Mailing Correspondence) EV332063858U ("Express Mail" Mailing Label Number)